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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' REPLY IN SUPPORT OF SECOND AMENDED MOTION TO SEAL DOCUMENTS FILED IN SUPORT OF ITS MOTION FOR SUMMARY JUDGMENT REGARDIGN PREEMPTION

(Assigned to the Honorable David G. Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") hereby submit this Reply in Support of its Second Amended Motion to Seal relating to documents filed in support of its Motion for Summary Judgment Regarding Preemption.

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The parties have resolved and Plaintiffs do not challenge many of the redactions made by Bard to the documents filed redacted under seal. There are less than 50 documents now at issue as addressed in Plaintiffs response.[1] Of those documents, Bard has redacted all of them to protect trade secrets and information recognized by the FDA and the Ninth Circuit as proper for sealing and protection from public dissemination. Plaintiffs' challenges to those redactions are without merit. As redacted, the documents meet the test of the balance necessary between the right of public access and the right to protect materials that "have traditionally been kept secret for important policy reasons." as recognized in *Kamakana v. City & Cnty. of Honolulu,* 447 F.3d 1172, 1179 (9th Cir. 2006) (quoting *Nixon v. Warner Commc'ns, Inc*., 435 U.S. 589, 597 & n. 7 (1978). Specifically Bard notes that many of the documents are cited to show that information was provided to the FDA during the regulatory clearance of the filters at issue. The redacted information does not prevent the Court or the public from understanding the motion or the Court's ruling.

The documents at issue as set forth on pages 10 -18 of Plaintiffs' Response fall into the following categories:

Information about testing of IVC filters

Plaintiffs' challenges to the following exhibits are all challenges to redaction of Bard's internal test methods, procedures, results and analysis. Bard made these redactions consistent with those made by FDA/FOIA to protect its internal test methods and analysis. The remainder of the documents are not redacted.

Carr 3 [Dkt 7730-1); 54 [Dkt 7330-3 at21]; 68 [Dkt. 7330-6 at 47]; 69 [Dkt. 7330-7 at 17]; 85 [Dkt. 7330-10 at 82}; 95 [Dkt. 7331 at 4]; 97 [Dkt. 7331 at 100]; and 118 [Dkt. 7332-3 at 35].

Van Vleet 4 [Dkt. 7332-9 at 4]; 6 [Dkt. 7332-9 at 9]; 8 [Dkt. 7332-9at 18]; 11

[1] Because the remaining redactions are not challenged and are redacted consistent with the redactions made by FDA/FOIA and the law in the Ninth Circuit, Bard requests that its motion be granted as those documents and they be accepted by the Clerk as filed redacted.

[Dkt7340-2 at 1]; 12 [Dkt. 7332 -10 at 52]; 13[Dkt. 7332-10 at 57]; 14 [Dkt. 7332-10 at 60]; 15 [Dkt. 7332-10 at 64]; 16 [Dkt. 7332-10 at 74]; 18 [Dkt. 7333 at 1]; 19a [Dkt. 7333 at 4]; 19b [Dkt. 7333-1 at 55]; 20 [Dkt. 7333-1 at 67]; 21 [Dkt. 7333-2 at 77]; 22 [Dkt. 7333-2 at 80]; 23 [Dkt. 7333-4 at 9]; 26a and 26b [Dkt. 7333-5 at 45 and 91]; 27 [Dkt. 7333-6 at 1]; 28 [Dkt. 7333-6 at 97]; 29 [Dkt. 7333-8 at 25} and 34 [Dkt. 7333-9 at 53]

Documents submitted to FDA and redacted consistent with FOIA productions

Plaintiffs' challenges to the following exhibits are all challenges to redactions of documents submitted to the FDA. Those redactions were made consistent with comparable productions by FDA. The document encompass thousands of pages, and Bard redacted only the test protocol, results and analysis. Plaintiffs make no showing that this is not accurate, and simply state that "Plaintiffs have agreed to redactions consistent with FOIA productions and argue Bard must redact in accordingly."[2]

Carr 89 [Dkt. 7330 0 at 82] ; Carr 102 [Dkt. 7331 at 138]

Van Vleet 5 [Dkt. 7442 at 1]

Van Vleet 32. It appears that this document was missed when Bard filed it motion and it was included in the group still under seal until the FDA and FOIA provide redactions. Bard will file it redacted consistent with prior FDA/FOIA productions.

Internal marketing, regulatory and business analysis

Carr 8 [Dkt 7730-1 at 25, Carr 32 [Dkt 7730-1 at 64] and Carr 34 [Dkt. 7330-1] all contain redactions of internal marketing and regulatory plans and analysis that were not provided to FDA, and an internal drafts of a letter that was eventually sent to doctors. The draft shows internal business analysis of the draft. That information is not necessary to understand the Court's ruling as the final letter is available publically.

Carr 74 [Dkt. 7330-8 at 96] contains redactions of internal marketing and regulatory analysis that is not available publically.

[2] Bard will continue to meet and confer with Plaintiffs on these exhibits in an attempt to reach a resolution on the redactions to them as it is not clear what Plaintiffs' objections are to the redactions made by Bard.

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Carr 79 [Dkt. 7330-8] and Carr 91 [Dkt. 7330-10 at 197] contain redactions of internal hand written notes and comments on drafts of documents. The internal comments address regulatory and marketing analysis not provided to the FDA.

Van Vleet 1 [Dkt 7332-8 at 1} contains internal product analysis.

Documents Bard did not or does not seek to seal

Plaintiffs contends that Carr 47 was not addressed in Bard's motion. That is because Bard is not seeking to redact or seal that document.

Upon further review, Bard will file Carr 61 [Dkt 7730-6 at 37], Carr 62 [Dkt 77830-6 at 42] , Carr 94 [Dkt 7331 at 1] and Van Vleet 7 [Dkt 7332-9 at 16] and does not seek to have those documents sealed or redacted.

ARGUMENT AND CITATION OF AUTHORITY

A. Bard has Established That Compelling Reasons Exist to Seal the Redacted Information

Plaintiffs allege in their response that Bard has failed to meet its burden to show compelling reasons to seal the redacted information because "Bard's motion is conspicuously devoid of any supporting affidavits, declarations or other evidence." (Dkt. 7712 at P. 4 and 5). However, attached to Bard's Seconded Amended Motion (and cited in it) is the Declaration of Robert Carr in which he specifically addresses the redacted confidential and trade secret information, the investment made by Bard to create the information and the procedures taken by Bard to protect it in the highly competitive medical device industry, and the harm to Bard if the information was made available to its competitors. (Dkt. 7335-1). As such, Plaintiffs' argument that the motion is not supported by evidence and citation to cases in which no evidence was provided to support are motion to seal are without merit and not applicable. To the contrary, Mr. Carr addresses the types of information at issue in Bard's motion, the resources and time Bard expended to develop them and the measures Bard takes to protect them.

Further, Bard has not redacted the documents to conceal broad categories of documents or information, and instead has made limited redactions of information

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recognized by the FDA and the Ninth Circuit as proper for sealing. See, in *In re Incretin-Based Therapies Products Liability Litigation*, No. 13MD2453 AJB (MDD), 2015 WL 11658712 (S.D. Cal. Nov. 18, 2015). The redactions do not impair the public interest in understanding the Court's ruling or the judicial process.[3] See, *Kamakana*, 447F. 3d at 1179

B. Bard has established that the Redacted Information Contains Bard's Trade Secrets and Other Confidential Information

In their response Plaintiffs argue, without support or and evidence, that the redacted information cannot characterized as trade secret. Again, Plaintiffs ignore the Declaration of Robert Carr in which he clearly establishes that the information is trade secret. Plaintiffs offer no evidence to contradict this other than speculation.

The redacted testing is not "standard testing validation protocols" as Plaintiffs argue. To the contrary, a review of the redacted testing information shows that the tests were developed internally at Bard or through a confidential relationship with a vendor. Internal test procedures, results and analysis are trade secrets and properly sealed. See, *Jochims v. Isuzu Motors, Ltd.*, 151 F.R.D. 338, 341 (S.D. Iowa 1993) in which the court sealed trial exhibits including "internal engineering standards, confidential information regarding advertising expenditures, and test reports relating to the design and development of the Trooper. They are the kind of technical and commercial information commonly subject to confidentiality orders in cases of this kind. Depriving these documents of their confidential status would be inimical to Isuzu's competitive interests." (Emphasis added). Similarly Bard's internal testing relating to the design and analysis of its filters should be sealed.

Moreover, the other categories of redacted information at issue have long been recognized as containing information that requires sealing. *See e.g.*, *Spectrum Pharm.*,

[3] In their response, Plaintiffs conflate the issue of sealing with their argument son the merits of Bard's motion for summary judgment. See for example Page 6 and FN 2 arguing that the exhibits are not relevant to the merits.

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Inc. v. Sandoz Inc., No. 2:12-CV-00111-GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014) (sealing among other "proprietary business plans" and "business practices," "actual and planned confidential communications with the FDA"); *Clark v. Metro. Life Ins. Co.*, 2010 WL 1006823 (D. Nev. Mar. 16, 2010) (sealing "confidential internal business deliberations, organization, and capabilities"); *Citizens Comm'n on Human Rights v. Food & Drug Admin.*, 1993 WL 1610471, *7 (C.D.Cal.1993) (A drug application to FDA "by definition contains trade secret information because it contains significant information about how a...drug product is formulated, chemically composed, manufactured, and quality controlled."), *aff'd in part & remanded in part on other grounds*, 45 F.3d 1325 (9th Cir.1995). *See also*, *Bracco Diagnostics, Inc. v. Amersham Health Inc.*, CIVA 3-6025FLW, 2007 WL 2085350 (D.N.J. July 18, 2007) ("regulatory correspondence" with the FDA, "cost and profit information," "unpublished clinical studies," and "internal analyses on products which are not intended for publication or dissemination"). This is precisely the type of information Bard has redacted and seeks to seal. Plaintiffs offer no evidence to contradict the Declaration of Robert Carr that the information still has value to Bard and should be sealed.

CONCLUSION

Therefore, compelling reasons exist for protection of Bard's documents, and the Court should grant Bard's Motion to Seal for the documents filed redacted. Further, the redactions do not impair the ability of the public to understand the judicial process, Bard's motion or any ruling by Bard respectfully requests that the Court enters an Order sealing the redactions in documents filed redacted in Dkt. 7330 and 7340, and the redactions in Declarations of Robert Carr and John Van Vleet and the Statement of Material Fact. (Dkt. 7343 and 7345).

This 28th day of September, 2017.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 28, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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